

Clean set of claims as amended:

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B5 1. A hemofiltration system comprising:
a hemofiltration machine having at least one flow control and a removable extracorporeal circuit, mounted in a removable cartridge, for circulating blood from an individual through a hemofilter to remove waste and to return blood and replacement fluid to the individual after removal of waste, the extracorporeal circuit including a waste discharge path to convey waste fluid to a waste receiving unit and a replacement fluid path for infusing replacement fluid into said individual, said replacement fluid path including a sterilizing filter positioned to prevent contaminants from being infused into said individual.

a 2. A system according to claim 1 wherein said sterilizing filter is an inline filter filtering all replacement fluid infused into said individual.

3. A system according to claim 2 wherein sterilizing filter is integrally connected to the replacement fluid path.

4. A system according to claim 2 wherein said replacement fluid path includes a connector upstream of said sterilizing filter for connecting to a replacement fluid reservoir.

5. A system according to claim 1 wherein said sterilizing filter includes a 0.2 micron filter medium.

6. A hemofiltration system comprising an extracorporeal circuit for circulating blood from an individual through a hemofilter to remove waste and to return blood and replacement fluid to the individual after removal of waste, the extracorporeal circuit

including a replacement fluid path to convey replacement fluid from a source to the extracorporeal circuit, the replacement fluid path including a sterilizing filter to avoid contamination of the extracorporeal circuit.

7. A system according to claim 6 wherein the source comprises at least one container holding replacement fluid.

8. A system according to claim 6 wherein the sterilizing filter is integrally connected to the replacement fluid path.

9. A system according to claim 6 wherein the replacement fluid path terminates in multiple fluid branches, each fluid branch including a connector to couple a source container of replacement fluid to the replacement fluid path.

10. A system according to claim 6 wherein the replacement fluid path includes a separate replacement fluid set comprising multiple branches, each branch including a connector to couple a source container of replacement fluid to the set, and wherein the replacement fluid path includes a set connector to releasably join the replacement fluid set to the replacement fluid path.

11. A system according to claim 10 wherein the sterilizing filter is in the separate replacement set.

12. A system according to claim 10 wherein the sterilizing filter is in the replacement fluid path upstream of the set connector.

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13. A hemofiltration system comprising a hemofiltration machine including a chassis and at least one flow controlling element on the chassis, an extracorporeal circuit for circulating blood from an individual through a hemofilter to remove waste and to return blood to the individual after removal of waste, a portion of the extracorporeal circuit being integrated, at least in part, within a fluid processing cartridge orienting the extracorporeal circuit for mounting as an integrated unit on the chassis with portions of the extracorporeal circuit in operating engagement with the flow controlling element and for removal as an integrated unit from the chassis, and a controller for the hemofiltration machine operable in a hemofiltration mode to operate the flow controlling element, when the fluid processing cartridge is mounted on the chassis, to convey an individual's blood through the extracorporeal fluid circuit to a hemofilter to remove waste fluid and to supply replacement fluid, the controller also operable in a dwell mode to suspend the hemofiltration mode and retain the fluid processing cartridge on the chassis between multiple intermittent hemofiltration sessions during a prescribed time period, the fluid processing cartridge including a sterilizing filter arranged to filter replacement fluid prior to infusion.

14. A system according to claim 13 wherein the extracorporeal circuit includes a waste discharge path to convey waste fluid to a waste receiving unit, the waste discharge path including an air break to prevent back flow of waste contaminants into the extracorporeal circuit from the waste receiving unit.

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Sub 35 15. A system according to claim 13 wherein the extracorporeal circuit includes a replacement fluid path to convey replacement fluid from a source to the extracorporeal circuit, said sterilizing filter being incorporated in said replacement fluid path to avoid contamination of the extracorporeal circuit.

16. A system according to claim 13 wherein, during the dwell mode, the controller operates the flow controlling element to introduce a bacteriostatic agent into the extracorporeal circuit.

17. A system according to claim 13 wherein, during the dwell mode, the controller subjects the extracorporeal circuit to refrigeration.

18. A system according to claim 13 wherein the controller registers duration of use of the extracorporeal circuit and prevents operation of the hemofiltration machine when the registered duration of use exceeds a predetermined period.

19. A system according to claim 13 wherein the controller registers use of the extracorporeal circuit and prevents operation of the hemofiltration machine when the registered use fails to correlate with predetermined criteria.

20. A system according to claim 13 wherein, during the hemofiltration mode, the controller operates the flow controlling element to convey blood through the hemofilter at a blood flow rate of at least 300 ml/min.

21. A method for carrying out hemofiltration comprising the steps of (i) operating a hemofiltration machine to convey an individual's blood through an extracorporeal fluid

circuit to a hemofilter to remove waste fluid, (ii) discharging waste fluid to a waste receiving unit through a waste discharge path that forms a part of the extracorporeal circuit, -and (iii) preventing back flow of waste contaminants into the extracorporeal circuit from the waste receiving unit by locating an air break in the waste discharge path.

22. A method according to claim 21 wherein steps (i), (ii), and (iii) are conducted during multiple intermittent sessions during a prescribed time period.

23. A method according to claim 22 further including the step of introducing a bacteriostatic agent into the extracorporeal circuit between the multiple intermittent sessions.

24. A method according to claim 22 further including the step of subjecting the extracorporeal circuit to refrigeration between the multiple intermittent sessions.

25. A method according to claim 22 wherein the prescribed time period is between about 48 hours and about 120 hours.

26. A method according to claim 22 wherein the prescribed time period is between about 72 hours and about 80 hours.

27. A method according to claim 21 further including the step of (iv) performing steps (i) to (iii) at least four times weekly.

28. A method according to claim 21 wherein, in step (i), blood is conveyed through the hemofilter at a blood flow rate of at least 300 ml/min.

29. A method for carrying out hemofiltration comprising the steps of (i) operating a hemofiltration machine to convey an individual's blood through an extracorporeal fluid

circuit to a hemofilter to remove waste fluid, (ii) introducing replacement fluid through a replacement fluid path that forms a part of the extracorporeal circuit, (iii) preventing contamination of the extracorporeal circuit by locating a sterilizing filter in the replacement fluid path.

30. A method according to claim 29 wherein steps (i), (ii), and (iii) are conducted during multiple intermittent sessions during a prescribed time period.

31. A method according to claim 30 further including the step of introducing a bacteriostatic agent into the extracorporeal circuit between the multiple intermittent sessions.

32. A method according to claim 30 further including the step of subjecting the extracorporeal circuit to refrigeration between the multiple intermittent sessions.

33. A method according to claim 30 wherein the prescribed time period is between about 48 hours and about 120 hours.

34. A method according to claim 30 wherein the prescribed time period is between about 72 hours and about 80 hours.

35. A method according to claim 29 further including the step of (iv) performing steps (i) to (iii) at least four times weekly.


36. A method according to claim 29 wherein, in step (i), blood is conveyed through the hemofilter at a blood flow rate of at least 300 ml/min.

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Respectfully submitted,

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